APR 25 2011

MEDI-TECH
International Corporation

Medi-Tech International Corp.
Protective Restraints

510(k) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION UPON WHICH AN EQUIVALENCE DETERMINATION COULD BE BASED

SUBMITTER INFORMATION

NAME:	Medi-Tech International Corp.	TELEPHONE:	718-875-4535
ADDRESS:	26 Court Street - Suite 1301	CONTACT:	Marilyn Geiger
	Brooklyn, NY 11242	DATE:	April 19, 2011

DEVICE NAMES:

NAME: Easy-View Mitts, Model #MTRM281

COMMON NAME: Protective Restraint

CLASSIFICATION NAME: Restraint, Protective (FMQ)

PREDICATE OR LEGALLY MARKETED DEVICE:

J.T.POSEY COMPANY Protective Restraint (K963413)

DEVICE DESCRIPTION:

The Medi-Tech International Corp. Protective Restraint is a protective restraint device which is intended for medical purposes to control the movement of a patient's hand or finger movements thereby enabling examination or protection of the patient or others.
Device Design Materials Used/Physical Properties:
The Medi-Tech Protective Restraint is designed similar to those marketed by other manufacturers.

DEVICE INTENDED FOR USE:

Medi-Tech International Corporations Protective Restraint is intended to be utilized as a patient safety device when patients are assessed at risk of disrupting life-saving treatments or could cause self-injury.

Medi-Tech International 510(k) Safety & Effectiveness Summary

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE

Characteristic	Medi-Tech International Corp. Device	Other Device
Materials	Primarily comprised of cotton and polyester material and polyester fiber filling	Same
Sizes	Target Population: Adult - Male or Female One Size (Universal) – fits all adults Fits either hand Not for Pediatric Use	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly agitated Treatment interference by patient	Same

SUBSTANTIAL EQUIVALENCE CLAIM:

Medi-Tech International Corp. Mitts are similar in indications, design and features to various Protective Restraints that the FDA has found to be substantially equivalent to pre-amendment devices. The following is such a device:

Manufacturer	Product	510(k) Number
J.T.Posey Company	Restraint, Protective	K963413

SUBSTANTIAL EQUIVALENCE COMPARISON:

	Medi-Tech International Corp.	J.T. Posey Company
Indication	Patients accessed at risk of disrupting life-saving treatments or self injury.	Patients accessed at risk of disrupting life-saving treatments or self injury.
Mode of Operation	Insert patient's hand. Wrap wrist strap around wrist.	Insert patient's hand. Wrap wrist strap around wrist.
Material	Cotton, Polyester & Polyester Fiber	Cotton, Polyester & Polyester Fiber
Sterility	Non-Sterile/Reusable	Non-Sterile/Reusable

The determination of substantial equivalence is not based upon an assessment of any performance data, clinical or non-clinical.

SUMMARY OF NON-CLINICAL DATA

The MTRM281 mitt was tested on Marilyn Geiger, Medi-Tech International Corporations Product Manager and found to be equivalent to the J.T. Posey predicate device:

Test: Safety - The flap opens easily to be able to view the back of the hand. The wrist strap was wrapped around the smallest part of the wrist, through the plastic ring and secured with the hook and loop fastener.

Result: The strap did not compromise circulation.

Test: Effectiveness - The hook and loop fastener was detached and the inspection flap was pulled back to expose the hand. The inspection flap was closed by tucking it into the end of the mitt and the hook and loop closure was pressed firmly together to close it.

Result: The inspection flap performs as intended to allow the visualization of the hand.

Test: Function - The strength of the strap was tested and was shown to limit the movement to the extent necessary for treatment, examination and to prevent self-injury or injury to others.

Result: The strength of the strap of the MTRM281 mitt was compared to the predicate device strap and provided similar results.

The non-clinical tests demonstrated that the MTRM281 mitt is as safe, as effective and functions the same and as well as the predicate device with no adverse effects or complications.

SUMMARY OF BENCH TESTING

Comparative bench testing was performed by the Intertek testing facility to evaluate the physical integrity and performance of the device and it's predicate.

Tests performed:

- FIBER CONTENT (ATTCC 20A)
- TEARING RESISTANCE OF FABRICS (ELMENDORF) - (ASTM D 1424)

Medi-Tech International 510(k) Safety & Effectiveness Summary

Tests performed: (continued)

- SHEAR STRENGTH OF HOOK & LOOP TOUCH FASTENERS (ASTM D 5169)
- PEEL STRENGTH OF HOOK & LOOP TOUCH FASTENERS (ASTM D 5170)
- BREAKING STRENGTH (ASTM D 5034)
- FAILURE IN SEWN SEAMS OF WOVEN APPAREL FABRICS (ASTM D 1683)
- PILLING RESISTANCE: RANDOM TUMBLE (ASTM D 3512)
- DIMENSIONAL STABILITY TO WASHING (AATCC 150)
- APPEARANCE AFTER WASHING (VISUAL)
- F.P. & L. ACT (16 CFR500 OR NIST UNIFORM LAWS & REGULATIONS
- HANDBOOK 130)
- COUNTRY OF ORIGIN MARKING (19 CFR 134.11)
- USE LABELING (VISUAL)
- CARE INSTRUCTIONS (16 CFR 423)
- DEFECTS (VISUAL CHECK)
- WORKMANSHIP (VISUAL CHECK)
- SHARP EDGES/SHARP POINTS (16 CFR 1500.48 SHARP POINT, 16 CFR 1500.49 •SHARP EDGES)
- FUNCTIONALITY (ITS-M0061)
- COLORFASTNESS TO ACCELERATED LAUNDERING (AATCC 61)
- COLORFASTNESS TO CHLORINE BLEACH (AATCC/ASTM TS-001)
- COLORFASTNESS TO NON-CHLORINE BLEACH (AATCC/ASTM TS-001)
- COLORFASTNESS TO PERSPIRATION (AATCC 15)
- COLORFASTNESS TO BURNT GAS FUMES (AATCC 23)

The bench test results demonstrate that the device satisfies all functional requirements and the device is as safe, as effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Marilyn Geiger
Medi- Tech International Corporation
26 Court Street - Suite 1301
Brooklyn, New York 11242

Re: K110377
Trade/Device Name: Protective Restraint
Regulation Number: 21 CFR 880.6760
Regulation Name: Protective Restraint
Regulatory Class: I
Product Code: FMQ
Dated: February 8, 2011
Received: February 10, 2011

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Dear Mr. Geiger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110377

Indications for Use

510(k) Number: K110377

Device Name: Protective Restraint, Easy-View Mitts #MTRM281

Indications For Use: Medi-Tech International Corporations Easy-View Mitts are intended to be utilized as a patient safety device when patients are assessed at risk of disrupting life-saving treatments or could cause self-injury.

Contraindication: Not for Pediatric Use

Prescription Use ___RX_____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R. C. Chapman 4/25/11

(Division Sign-Off)
)ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K110377